

REMARKS

I. Introduction

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1-8 are requested to be canceled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Support for amendments to claim 9 can be found in Examples 1 and 2 of the Specification.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 9-12 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 9-12 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Office previously indicated that this rejection was overcome by Applicants previous amendments. See Advisory Action, point 5. In light of the Advisory Action, Applicants believe this rejection is moot.

b. Claim Rejections - 35 U.S.C. § 103

Claims 9-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Zgoulli (US 5,456,985) in view of Matsukawa (US 3,660,304). In addition, claims 9-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Grisoni (WO 02/24319) (US equivalent 7,067,153) in view of Iwasaki (US 4,349,454) or Zgoulli (US 5,456,985).

i. Current Obviousness Standard

The Supreme Court recently reaffirmed the Graham factors for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* (No. 04-1350) (U.S., April 30, 2007). The Graham factors, as outlined by the Supreme Court in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966), are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; 3) resolving the level of ordinary skill in the pertinent art; and 4) evaluating evidence of secondary consideration. The Supreme Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a), and held that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions. The Court noted that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed, and specifically stated:

Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was ***an apparent reason to combine the known elements in the fashion claimed*** by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., slip op. at 14 (emphasis added). As discussed below, the cited art cannot render the claimed invention obvious.

ii. Advisory Action and Applicants Amendments

The Office maintains, “The present claims recite the transition phrase ‘comprising of’, and therefore, do not preclude the present [sic] of the gastro-retentive polymer. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims.” Advisory Action, p. 3.

As an initial matter, Applicants note that the current claims do not contain the phrase “comprising of.” While current claim 9 does contain the term “comprising,” this phrase is provided in connection with the steps of the currently claimed method and does not relate to the compounds in the particular solutions begin described.

The Office appears to maintain that Zgoulli teaches the current method because the current method allegedly does not preclude the presence of gastric resistant polymer in the aqueous solution of gum arabic. In order to expedite prosecution, Applicants have amended claim 9 to indicate that an oil-based water immiscible material is added to a solution consisting essentially of gum arabic. This addition to the claim clarifies that no enteric anionic cellulose derivatives are present in the gum arabic.

iii. Zgoulli in view of Matsukawa

According to the present invention, an oil-based water-immiscible core material is first suspended in an aqueous solution consisting essentially of gum arabic, and then added to an aqueous solution of an enteric anionic derivative. Because the oil-based core material and gum arabic are mixed in advance, the suspension of the oil-based core material is stabilized in the presence of the gum arabic as protective colloid. As a result, complex coacervation occurs between the anionic cellulose derivative and the gum arabic which has absorbed on the oil-based core material and has been suspended, thereby allowing a microcapsule comprising shell material which comprises both of the polymers to be obtained (page 12 lines 5-13).

According to Zgoulli, an oil is added into a mixture of a gastro-resistant polymer (such as CAP) and gum arabic to form a microcapsule (column 6 lines 58-62). Accordingly, Zgoulli has a different order of addition from the present invention leading to a product with different physical characteristics from compositions derived using the current method. In

other words, Zgoulli first mixes the enteric anionic cellulose derivative with gum arabic and later adds the oil. The current application first mixes the oil based water immiscible core material with gum arabic and later introduces the enteric cellulose derivative. When the gastro-resistant polymer and the gum arabic are mixed in advance in the absence of oil, a complex is formed so that the later added oil is prevented from being enclosed suitably.

The Office has questioned whether the current claims, in fact, provide a different result from Zgoulli. See Office Action dated July 23, 2007, pp. 5-6. Applicants submitted a Declaration from Miyuki Fukasawa showing that the methodology of Zgoulli produces a different result from the currently claimed methodology. As the declaration provides, in point 3, mixing the enteric anionic derivative and the gum arabic as provided in Zgoulli resulted in the separation of the oil based material from the cellulose derivative and the gum arabic. In contrast, the currently claimed method, as shown in the Examples, allows for effective formation of the microcapsule.

Applicants also maintain that the Office's attempt to use the current specification as the basis for an obviousness rejection is inappropriate. See Office Action dated July 23, 2007, p. 5, last 3 lines. Only prior art available under section 102 may be properly used as the basis for an obviousness rejection. Applicants' own specification does not fulfill these requirements and should not be the basis for any arguments in the obviousness rejection.

In Matsukawa, a mixture of a shell-forming material such as polymethylmethacrylate and core material was gradually added to a solution of gum arabic to form a microcapsule (See Example I). Thus, Matsukawa is silent about an enteric anionic cellulose derivative. According to Matsukawa, the shell-forming material is dissolved in a low boiling point solvent (primary solution) which is organic (column 2 lines 2-4, column 2 line 62 to column 3 line 6). As described in the present specification, the organic solvent has numerous problems including organic residue and operational safety (page 3 lines 6-9). In the present invention, the solvent is not used (page 3 line 25 to page 4 line 5).

Applicant respectfully requests reconsideration and withdrawal of the rejection.

iv. Grisoni in view of Iwasaki or Zgoulli

According to Grisoni, a mixture of a hydrophilic polymer and an oil component is heated above the gel temperature of the hydrophilic polymer and then cooled to a temperature below the gel point of the hydrophilic polymer to form a microcapsule (column 13 lines 17-55). Thus, Grisoni takes advantage of the thermal gelation phenomenon. As the Examiner indicates, Grisoni is silent regarding the use of gum arabic. Moreover, although hydroxypropylmethyl cellulose and phthalate (HPMCP) is listed as one of hydrophilic polymers (column 3 lines 50-51), HPMCP cannot product a microcapsule according to the Grisoni methodology described above, because HPMCP does not gel thermally.

The Office attempts to remedy the deficiencies of Grisoni with Iwasaki and Zgoulli. However, Applicants believe that Iwasaki and Zgoulli provides results that must be considered during any analysis of whether the claims are obvious. See MPEP § 2143.01. It is well settled law that prior art teaching away from the claimed invention is highly relevant in any determination of whether the claimed invention would have been obvious. See, for example, *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Iwasaki teaches the use of a hydrophobic organic solvent (See, for example, the Abstract). As described above, one of the objects of the present invention is to avoid using an organic solvent. Thus, Iwasaki never teaches the present invention and directs a person skilled in the art to conditions outside the current invention.

As provided above, Zgoulli has a different order of addition from the present invention leading to a product with different physical characteristics from compositions derived using the current method. Accordingly, Zgoulli does not teach the current method and the other references combined with the methodology of Zgoulli will lead to a different product than the currently claimed method. Based on the above, the claims of the current invention are not obvious over the teachings Grisoni, Iwasaki, and Zgoulli.

The Office argues:

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, nor is it that the claimed invention must be expressly suggested in

any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

Office Action dated July 23, 2007, p. 6. Applicants have provided above a summary of the current obviousness standard. The current standard requires a complete consideration of the prior art along with secondary considerations. Evidence in the prior art teaching away from the invention must also be considered. *United States v. Adams*, 383 U.S. 39, 40, 148 USPQ 479, 480 (1966). In addition, the proposed modifications to the prior art cannot render the prior art unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900 (Fed.Cir. 1984) and also, see MPEP § 2143.03. Therefore, the above provided arguments should be considered and render the current invention non-obvious over the cited prior art whether considered alone or in combination.

Applicant respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 1/23/08

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